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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,554	10/06/2000	John F. Engelhardt	875.024US1	4157

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/26/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,554

Applicant(s)

ENGELHARDT ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The Preliminary Amendment filed June 11, 2002 (Paper No. 8) in response to the Election/Restriction requirement of December 4, 2001 (Paper No. 6) is acknowledged and has been entered. Claims 46-48 have been added, therefore claims 1-48 are pending.

Upon review and reconsideration in view of Applicant's response to the Election/Restriction requirement of Paper No. 6, the following new Election/Restriction requirement is made taking into account the newly added claims. The new Election/Restriction should address Applicant's arguments regarding the closely linked structural elements among the groups, linking claim practice has been applied among the groups. Any inconvenience this may have caused Applicant's is regretted.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1*, 2, 3, 24, 25, drawn to a composition comprising two recombinant AAV DNA molecules and a host cell, classified in class 435, subclass 320.1.
- II. Claims 1*, 4-7, 9, 10, 11, 46*, 47*, drawn to drawn to a composition comprising two recombinant AAV DNA molecules which include an additional structural element, a promoter which is linked to an open reading frame, classified in class 536, subclass 24.1.
- III. Claims 1*, 8, 46*, 47*, drawn to a composition comprising two recombinant AAV DNA molecules which include an additional structural element, an enhancer, classified in class 536, subclass 24.1.

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- IV. Claim 1*, 8, 10, 11, 46*, 47*, drawn to a composition comprising two recombinant AAV DNA molecules which includes additional structural elements one DNA contains an enhancer and the other DNA contains a promoter, classified in class 536, subclass 24.1.
- V. Claims 1*, 12-17, 23, drawn to a composition comprising two recombinant AAV DNA molecules which includes an additional structural elements one DNA contains an origin of replication and the other DNA contains a promoter, classified in class 536, subclass 24.1.
- VI. Claims 18, 45, drawn to a composition comprising a recombinant AAV DNA molecules which includes a heterologous origin of replication, classified in class 435 subclass 320.1.
- VII. Claims 19, 20, 23, drawn to a composition comprising a recombinant AAV DNA containing molecule which includes a heterologous transcriptional element, a promoter, the vector does not comprise sequences which encode ^{a protein}, classified in class 435, subclass 320.1.
- VIII. Claims 19, 21, 23, drawn to a composition comprising a recombinant AAV DNA containing molecule which includes a heterologous transcriptional element, a promoter, the vector does not comprise sequences which encode ^{a protein}, classified in class 435, subclass 320.1.
- IX. Claims 22, 44, drawn to a composition comprising a recombinant AAV DNA containing molecule which encodes a protein that binds an origin of replication

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but makes no requirement that there be an origin of replication present on the same DNA molecule, classified in class 435, subclass 320.1.

- X. Claims 26* and 27*, drawn to a method of transferring the recombinant DNA to a host cell using a composition comprising two recombinant AAV DNA molecules, classified in class 435, subclass 455.
- XI. Claims 26*, 27*, 28-31, 33, 35, 37, 48*, drawn to a method of transferring the recombinant DNA to a host cell using a composition comprising two recombinant AAV DNA molecules which include an additional structural element, a promoter which is linked to an open reading frame, classified in class 435, subclass 455.
- XII. Claims 26*, 27*, 32, 34, 48*, drawn to a method of transferring the recombinant DNA to a host cell using a composition comprising two recombinant AAV DNA molecules which include an additional structural element, an enhancer, classified in class 435, subclass 455.
- XIII. Claim 26*, 27*, 32, 34, 36, 48*, drawn to a method of transferring the recombinant DNA to a host cell using a composition comprising two recombinant AAV DNA molecules which includes an additional structural element one DNA contains an enhancer and the other DNA contains a promoter, classified in class 435, subclass 455.
- XIV. Claims 26*, 27*, 38-40, drawn to a method of transferring the recombinant DNA to a host cell using a composition comprising two recombinant AAV DNA molecules which includes additional structural elements one DNA contains an

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origin of replication and the other DNA contains a promoter, classified in class 435, subclass 455.

- XV. Claims 26*, 27*, 41-43, drawn to a method of transferring the recombinant DNA to a host cell using a composition comprising two recombinant AAV DNA molecules which includes additional structural elements one DNA element contains a sequences encoding a protein that binds to an origin of replication and the other DNA contains a promoter, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IX are compositions and are distinct from groups X-XV which are drawn to methods. Groups I-IX are compositions and each is distinct from the other because they contain different DNA sequences, each DNA having its own unique structure. Groups I-V are drawn to a composition that comprises two recombinant AAV. Although there are similarities between the groups, each group contains different structural elements that are not present in the other group. Group I contains two recombinant AAV DNA molecules wherein each DNA comprises non-AAV DNA and the two non-DNA sequences are not the same. Group II contains a promoter; promoters are DNA regions that recognize RNA polymerase. Group III contains an enhancer; enhancers boost the transcription of recombinant DNA they may be present anywhere and are not orientation dependent. Group VI requires that a promoter and an enhancer be present on a different DNA molecules. Group V requires an origin of replication, which differs from the transcription enhancing elements, an origin of replication defines the beginning of DNA replication. Group VI is a single recombinant AAV that contain a a heterologous origin of replication. Group VII is a single recombinant AAV that contain a promoter but does not contain

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an open reading frame, while Group VIII is a single recombinant AAV that contain an enhancer but does not contain an open reading frame. Group IX is a single recombinant AAV that encodes a protein that binds to an origin of replication. Because of the structural differences among the compositions, the search for one group will not be coextensive with that of the other group. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification or divergent subject, restriction for examination purposes as indicated is proper.

Groups X-XV are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not expected to be the same. Because of the structural differences among the compositions required for the methods, the search for one group will not be coextensive with that of the other group, restriction for examination purposes as indicated is proper.

Claims 1, 24 and 25 link(s) inventions I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 24 and 25. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a

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restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 46 and 47 link(s) inventions II-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 46 and 47. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 19 link(s) inventions VII and VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the

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continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 26 and 27 link(s) inventions X-XV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 26 and 27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 48 link(s) inventions XI-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 48. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable

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linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D. 8/23/02